IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BOARD OF REGENTS, THE UNIVERSITY OF TEXAS SYSTEM, and TISSUEGEN, INC., Plaintiffs, v. BOSTON SCIENTIFIC CORPORATION, Defendant.	Case No. 18-392-MN

ANSWER TO FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Defendant Boston Scientific Corporation ("Boston Scientific"), by and through its undersigned counsel, hereby answers the First Amended Complaint for Patent Infringement of Plaintiffs Board of Regents, the University of Texas System, and TissueGen, Inc. (D.I. 124.)

As set forth below, Boston Scientific answers the allegations in the First Amended Complaint by reproducing each of the pertinent headings. Boston Scientific's reproduction of any material set forth in the First Amended Complaint is solely for the purpose of convenience and is not, and should not be construed as, an admission by Boston Scientific that any allegations or other statements in the First Amended Complaint, whether explicit or implicit, are true, correct, or admitted by Boston Scientific. Except as specifically admitted, Boston Scientific denies each of the allegations in the First Amended Complaint.

The first page of the First Amended Complaint contains no allegations and, therefore, no response is required. To the extent a response is required, Boston Scientific denies any allegations in the first page of the First Amended Complaint.

INTRODUCTION

A. THE PARTIES

1. Boston Scientific admits that Claim 1 of the '296 patent recites "A composition comprising at least one biodegradable polymer fiber wherein said fiber is composed of a first phase and a second phase, the first and second phases being immiscible, and wherein the second phase comprises one or more therapeutic agents." Boston Scientific is without knowledge or information sufficient to form a belief as to the remaining allegations in paragraph 1, and therefore denies the same.

2. Boston Scientific is without knowledge or information sufficient to form a belief as to the allegations in paragraph 2, and therefore denies the same.

3. Boston Scientific admits that it is a Delaware corporation with a headquarters in Marlborough, Massachusetts. Boston Scientific admits that it has made, marketed, and distributed SYNERGY Stents after it received FDA approval in 2015. Boston Scientific admits that the SYNERGY metallic stent is made of a Platinum Chromium alloy (PtCr), and has an abluminal biodegradable polymer coating that includes everolimus-rich domains (i.e. domains with both everolimus and PLGA polymer dissolved into each other) and 85:15 PLGA-rich domains (i.e. domains with both PLGA polymer and everolimus dissolved into each other). Boston Scientific admits that, in submissions to the FDA, Boston Scientific represented that SYNERGY Stents are available in stent lengths of 8, 12, 16, 20, 24, 28, 32, 38, and 48 mm and stent diameters of 2.25, 2.50, 2.75, 3.00, 3.50, 4.00, 4.50, and 5.00 mm, depending on the stent length. Boston Scientific admits that, in submissions to the FDA, Boston Scientific represented that the "Stent Strut Thickness" of SYNERGY Stents was 0.074 mm for diameters 2.25 mm to 2.75 mm, 0.079 mm for diameters 3.00 mm to 3.50 mm, and 0.081 mm for diameters of 4.00 mm to 5.00 mm. Boston Scientific denies the remaining allegations in paragraph 3, including to the extent the allegations

suggest that the SYNERGY Stent includes a biodegradable polymer fiber, a first phase and a second phase, and first and second phases that are immiscible.

4. Boston Scientific admits that the graphic labeled "The SYNERGY Stent" in paragraph 4 of the First Amended Complaint purports to be a page of a presentation entitled "Final five-year clinical outcomes in the EVOLVE trial: A randomised evaluation of a novel bioabsorbable polymer-coated, everolimus-eluting stent" (the "Presentation") which is available at the URL identified in paragraph. Boston Scientific admits that a portion of the Presentation includes a field emission scanning electron microscopy (FESEM) image at approximately 10,000 times magnification, with the label "PLGA rich domain" (i.e. domain with both PLGA polymer and drug dissolved into each other) and the label "Drug rich domain" (i.e. domain with both drug and PLGA polymer dissolved into each other). To the extent the allegations in paragraph 4 attempt to characterize the Presentation, Boston Scientific denies that characterization. Boston Scientific denies the remaining allegations in paragraph 4, including to the extent the allegations suggest that the SYNERGY Stent includes a biodegradable polymer fiber, a first phase and a second phase, and first and second phases that are immiscible.

5. Boston Scientific admits that, after Boston Scientific received FDA approval in 2015, Boston Scientific has marketed and distributed SYNERGY Stents in the United States under the trade names SYNERGY™ Monorail™ Everolimus-Eluting Platinum Chromium Coronary Stent System, SYNERGY™ Over-the-Wire Everolimus-Eluting Platinum Chromium Coronary Stent System, and SYNERGY™ XD Monorail™ Everolimus-Eluting Platinum Chromium Coronary Stent System under the UPNs identified by Boston Scientific in response to Plaintiffs' Interrogatory No. 2 and all supplemental responses thereto, including the UPNs listed in the spreadsheet Boston Scientific produced in response, bearing bates number BSC-UTEX-00109825.

Boston Scientific admits that the SYNERGY Stents were authorized under FDA premarket approval (PMA) No. P150003 and supplements S001 to S062. Boston Scientific admits that, as a general matter, it has provided Directions for Use for SYNERGY Stents. Boston Scientific denies the remaining allegations in paragraph 5.

6. Boston Scientific admits that, after Boston Scientific received FDA approval in 2015, Boston Scientific has maintained manufacturing and distribution operations concerning SYNERGY Stents in Ireland and in the United States, including in Minnesota and Massachusetts; imported SYNERGY Stents into the United States; sold or offered to sell SYNERGY Stents in the United States; and made SYNERGY Stents in the United States, including the preparation of and application of the abluminal polymer coating to the SYNERGY stents. Boston Scientific denies the remaining allegations in paragraph 6.

B. JURISDICTION AND VENUE

7. The allegations in paragraph 7 are legal conclusions to which no answer is required. To the extent an answer is required, Boston Scientific admits that this Court has subject matter jurisdiction over this controversy pursuant to 28 U.S.C. §§ 1331 and 1338(a). Boston Scientific denies that there is subject matter jurisdiction over claims brought by the Board of Regents for the University of Texas System. Boston Scientific admits that it is subject to the Court's personal jurisdiction for purposes of this action only, but Boston Scientific denies the merit and validity of any of the Plaintiffs' claims for which personal jurisdiction may be had. Boston Scientific admits that venue is proper in this District. Boston Scientific denies the remaining allegations in paragraph 7.

8. The allegations in paragraph 8 are legal conclusions to which no answer is required. To the extent an answer is required, Boston Scientific is without knowledge or information sufficient to form a belief as to the allegations in paragraph 8, and therefore denies the same.

C. HISTORY OF ANGIOPLASTY AND STENTING

9. Boston Scientific admits that, as a general matter, coronary artery disease is one of the leading causes of morbidity and mortality. Boston Scientific admits that, as a general matter, coronary arteries supply blood, oxygen, and nutrients to the heart. Boston Scientific admits that, as a general matter, coronary artery disease can develop when the major blood vessels that supply the heart become damages or clogged as part of the atherosclerotic process, which includes plaque buildup and inflammation. Boston Scientific admits that, as a general matter, narrowing of coronary arteries can decrease blood flow to the heart and that a complete blockage can cause heart attacks. Boston Scientific is without knowledge or information sufficient to form a belief as to the remaining allegations in paragraph 9, and therefore denies the same.

10. Boston Scientific admits that, as a general matter, narrowing in the coronary arteries can be treated with minimally invasive percutaneous coronary intervention ("PCI"). Boston Scientific admits that, as a general matter, PCI may involve both balloon angioplasty and stent implantation. Boston Scientific admits that, as a general matter, in the past, angioplasty could be performed without stent deployment, which some may refer to as balloon angioplasty. Boston Scientific admits that, as a general matter, balloon angioplasty procedures could have issues such as early elastic recoil, coronary dissection, and restenosis. Boston Scientific admits that, as a general matter, coronary stents were developed in part in response to perceived limitations of balloon angioplasty. Boston Scientific is without knowledge or information sufficient to form a belief as to the remaining allegations in paragraph 10, and therefore denies the same.

11. Boston Scientific admits that, in its Form 10-K Annual Report submitted to the SEC for the fiscal year ended December 31, 2009, Boston Scientific disclosed a "$716 million payment to Johnson & Johnson," but denies that it agreed to pay $716 million for alleged infringement relating solely to Dr. Palmaz's purported patented invention. Boston Scientific is without

knowledge or information sufficient to form a belief as to the remaining allegations in paragraph 11, and therefore denies the same.

12. Boston Scientific admits that, as a general matter, bare metal stents may have issues, including a risk of in-stent restenosis ("ISR"), which can be associated with morbidity and mortality. Boston Scientific admits that, as a general matter, reducing in-stent restenosis risk by adding a drug to the stent was a reason for drug-eluting stents. Boston Scientific is without knowledge or information sufficient to form a belief as to the remaining allegations in paragraph 12, and therefore denies the same.

13. Boston Scientific admits that, as a general matter, first and second generation drug eluting stents were designed to enclose bare metal stents in permanent polymers mixed with drugs. Boston Scientific is without knowledge or information sufficient to form a belief as to the remaining allegations in the first sentence of paragraph 13, and therefore denies the same. Boston Scientific is without knowledge or information sufficient to form a belief as to the second sentence of paragraph 13, and therefore denies the same. Boston Scientific denies the last sentence of paragraph 13.

14. Boston Scientific admits that the Taxus Express2 paclitaxel-eluting coronary stent was the first drug-eluting stent offered commercially by Boston Scientific in the United States. Boston Scientific admits that the Taxus Express2 paclitaxel-eluting coronary stent was approved by the FDA on March 4, 2004 under FDA premarket approval (PMA) No. P030025. Boston Scientific admits that, in 2006, Boston Scientific paid approximately $540 million dollars to acquire Guidant's everolimus-eluting stent technology. Boston Scientific admits that the Promus everolimus eluting coronary stent was approved by the FDA on July 2, 2008 under FDA premarket approval (PMA) No. P070015 for applicant Abbott Vascular Inc. Boston Scientific admits that

Boston Scientific added the Promus everolimus-eluting coronary stent to Boston Scientific's portfolio under the Promus name. Boston Scientific denies the remaining allegations in paragraph 14.

15. Boston Scientific admits that, as a general matter, the Taxus Express2 and Promus stents are both drug-eluting stents with a conformal permanent polymer coating. Boston Scientific denies the remaining allegations in paragraph 15.

16. Boston Scientific admits that, as a general matter, the Summary of Safety And Effectiveness Data (SSED) maintained by the FDA for the medical device approved under PMA No. P030025 accurately describes the device approved under PMA No. P030025. Boston Scientific admits that what appears to be the SSED for the medical device approved under PMA No. P030025 is available at the URL identified in paragraph 16. Boston Scientific admits that a portion of the SSED states "The drug component of the TAXUS Express^2 Paclitaxel-eluting Coronary Stent System (referred to as the TAXUS Express Stent) consists of paclitaxel (the active ingredient) and Translute™ polymer carrier (the inactive ingredient)" and "The drug/polymer coating is adhered to the entire surface (i.e., luminal and abluminal) of the stent." To the extent the allegations in paragraph 16 attempt to characterize the SSED available at the URL identified in paragraph 16, Boston Scientific denies that characterization. Boston Scientific denies the remaining allegations in paragraph 16.

17. Boston Scientific admits that, as a general matter, the Summary of Safety And Effectiveness Data (SSED) maintained by the FDA for the medical device approved under PMA No. P070015 accurately describes the device approved under PMA No. P070015. Boston Scientific admits that what appears to be the SSED for the medical device approved under PMA No. P070015 is available at the URL identified in paragraph 17. Boston Scientific admits that a

portion of the SSED states "The XIENCE V Everolimus Eluting Coronary Stent (XIENCE V stent) is coated with everolimus (active ingredient), embedded in a non-erodible polymer (inactive ingredient)" and "The drug matrix copolymer is mixed with everolimus (83%/17% w/w polymer / everolimus ratio) and applied to the entire PBMA coated stent surface." To the extent the allegations in paragraph 17 attempt to characterize the SSED available at the URL identified in paragraph 17, Boston Scientific denies that characterization. Boston Scientific denies the remaining allegations in paragraph 17.

18. Boston Scientific admits the allegations in paragraph 18.

19. Boston Scientific is without knowledge or information sufficient to form a belief as to the allegations in paragraph 19, and therefore denies the same.

20. Boston Scientific admits that, as a general matter, poly n-butyl methacrylate ("PBMA") is a non-erodible polymer.

21. Boston Scientific admits that, as a general matter, the polymer marketed under the tradename Translute™ is a non-erodible polymer.

22. Boston Scientific admits that, as a general matter, PVDF-HFP is a non-erodible semi-crystalline random copolymer.

23. Boston Scientific admits that, as a general matter, each of the polymers identified in paragraphs 20 through 22 are permanent polymers. Boston Scientific is without knowledge or information sufficient to form a belief as to the allegations in paragraph 19, and therefore denies the same.

24. Boston Scientific admits that as of December 31, 2009 and today, it has not developed or commercialized technology for controlled delivery of anti-proliferation compounds from an ultrathin biodegradable polymer fiber. However, Boston Scientific denies that other third

parties had not developed or commercialized technology for controlled delivery of anti-proliferation compounds from an ultrathin biodegradable polymer fiber by December 31, 2009. Boston Scientific denies the remaining allegations in paragraph 24.

D. DR. NELSON'S DRUG-ELUTING FIBER INNOVATION

25. Boston Scientific is without knowledge or information sufficient to form a belief regarding the allegations in paragraph 25, and therefore denies the same.

26. Boston Scientific is without knowledge or information sufficient to form a belief regarding the allegations in paragraph 26, and therefore denies the same. As to footnote 1, Boston Scientific admits that Boston Scientific SciMed, Inc. is the assignee of U.S. Patent App. No. 09/910,288, filed July 20, 2001, which issued as U.S. Patent No. 8,067,022 on November 29, 2011. Boston Scientific denies the remaining allegations in footnote 1.

27. Boston Scientific is without knowledge or information sufficient to form a belief regarding the allegations in paragraph 27, and therefore denies the same.

28. Boston Scientific is without knowledge or information sufficient to form a belief regarding the allegations in paragraph 28, and therefore denies the same.

29. Boston Scientific is without knowledge or information sufficient to form a belief regarding the allegations in paragraph 29, and therefore denies the same.

E. THE '296 PATENT

30. Boston Scientific admits that U.S. Patent Application No. 09/632,457's filing date is August 4, 2000, it lists seven individuals as inventors, and is entitled "Drug Releasing Biodegradable Fiber Implant." Boston Scientific admits that U.S. Patent Application No. 09/632,457 issued as the '296 patent, and claims priority to U.S. Provisional Patent application No. 60/147,827, which has a filing date of August 6, 1999. Boston Scientific admits that a document that appears to be a copy of the '296 patent was attached as Exhibit A to Plaintiffs'

Original Complaint for Patent Infringement (D.I. 1). Boston Scientific is without knowledge or information sufficient to form a belief regarding the remaining allegations in paragraph 30, and therefore denies the same.

31. Boston Scientific admits that claim 11 of the '296 patent depends from claim 1 of the '296 patent. Boston Scientific admits that claim 1 of the '296 patent recites: "A composition comprising at least one biodegradable polymer fiber wherein said fiber is composed of a first phase and a second phase, the first and second phases being immiscible, and wherein the second phase comprises one or more therapeutic agents." Boston Scientific admits that claim 11 of the '296 patent recites: "The composition of claim 1, wherein said one or more therapeutic agents are selected from the group consisting of drugs, proteins, enzymes, growth factors, immunomodulators, compounds promoting angiogenesis, compounds inhibiting angiogenesis, anti-inflammatory compounds, antibiotics, cytokines, anti-coagulation agents, procoagulation agents, chemotactic agents, agents to promote apoptosis, agents to inhibit apoptosis, and mitogenic agents." To the extent the allegations in paragraph 31 attempt to characterize the claims of the '296 patent, Boston Scientific denies that characterization. Boston Scientific denies the remaining allegations in paragraph 31.

32. Boston Scientific admits that claim 12 of the '296 patent depends from claim 1 of the '296 patent. Boston Scientific admits that claim 1 of the '296 patent recites: "A composition comprising at least one biodegradable polymer fiber wherein said fiber is composed of a first phase and a second phase, the first and second phases being immiscible, and wherein the second phase comprises one or more therapeutic agents." Boston Scientific admits that claim 12 of the '296 patent recites: "The composition of claim 1, wherein said one or more therapeutic agents include a radioactive agent or a contrast agent for imaging studies." To the extent the allegations in

paragraph 32 attempt to characterize the claims of the '296 patent, Boston Scientific denies that characterization. Boston Scientific denies the remaining allegations in paragraph 32.

33. Boston Scientific admits that claim 17 of the '296 patent depends from claim 16 of the '296 patent, which depends from claim 1 of the '296 patent. Boston Scientific admits that claim 1 of the '296 patent recites: "A composition comprising at least one biodegradable polymer fiber wherein said fiber is composed of a first phase and a second phase, the first and second phases being immiscible, and wherein the second phase comprises one or more therapeutic agents." Boston Scientific admits that claim 16 of the '296 patent recites: "The composition of claim 1, wherein said biodegradable polymer is a single polymer, a co-polymer, or a mixture of polymers selected from the group consisting of polypeptides, polydepsipeptides, nylon copolyamides, aliphatic polyesters, polydihydropyrans, polyphosphazenes, poly(ortho ester), poly(cyano acrylates), polyanhydride, modified polysaccharides and modified proteins." Boston Scientific admits that claim 17 of the '296 patent recites: "The composition of claim 16, wherein said aliphatic polyesters are selected from the group consisting of poly(glycolic acid), poly(lactic acid), poly(alkylene succinates) poly(hydroxybutyrate), poly(butylene diglycolate), poly(epsilon-caprolactone) and copolymers, blends and mixtures thereof." To the extent the allegations in paragraph 33 attempt to characterize the claims of the '296 patent, Boston Scientific denies that characterization. Boston Scientific denies the remaining allegations in paragraph 33.

34. Boston Scientific admits that claim 26 of the '296 patent depends from claim 1 of the '296 patent. Boston Scientific admits that claim 1 of the '296 patent recites: "A composition comprising at least one biodegradable polymer fiber wherein said fiber is composed of a first phase and a second phase, the first and second phases being immiscible, and wherein the second phase comprises one or more therapeutic agents." Boston Scientific admits that claim 26 of the '296

patent recites: "The composition of claim 1, wherein said one or more therapeutic agents are released at varying rates over time from said fiber." To the extent the allegations in paragraph 34 attempt to characterize the claims of the '296 patent, Boston Scientific denies that characterization. Boston Scientific denies the remaining allegations in paragraph 34.

35. Boston Scientific admits that the '296 patent includes figures labeled "FIG. 1," "FIG. 3a," "FIG. 3b," and "FIG. 4." Boston Scientific admits that the '296 patent includes sections titled "BRIEF DESCRIPTION OF THE DRAWINGS" and "DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS." Boston Scientific admits that the '296 patent includes sections titled "Example 3 Fabrication of Polymer Fibers with Concentric Coatings" and "Example 7 Preparation and Use of Polymer Stents." To the extent the allegations in paragraph 35 attempt to characterize the '296 patent, Boston Scientific denies that characterization. Boston Scientific denies the remaining allegations in paragraph 35.

36. Boston Scientific admits that the graphic labeled FIG. 1 in paragraph 36 appears to be FIG. 1 of the '296 patent. Boston Scientific admits that the graphic labeled FIG. 3a in paragraph 36 appears to be FIG. 3a of the '296 patent. Boston Scientific admits that the graphic labeled FIG. 3b in paragraph 36 appears to be FIG. 3b of the '296 patent. To the extent the allegations in paragraph 36 attempt to characterize the '296 patent, Boston Scientific denies that characterization. Boston Scientific denies the remaining allegations in paragraph 36.

37. Boston Scientific admits that a portion of the '296 patent states "FIG. 1: Shows fibers configured in a complex three-dimensional woven scaffolding with patterning. Each of the individual fibers may be loaded with one or more therapeutic agents. The numerals 21-27 denote fibers loaded with therapeutic agents." To the extent the allegations in paragraph 37 attempt to

characterize the '296 patent, Boston Scientific denies that characterization. Boston Scientific denies the remaining allegations in paragraph 37.

38. Boston Scientific admits that a portion of the '296 patent states "FIG. 3A and FIG. 3B: Fibers can provide the body with short term mechanical support in such applications as stents. FIG. 3A illustrates that a single polymer fiber can maintain the lumen of any tubular body, such as arteries, veins, or ducts. FIG. 3B illustrates that multiple polymer fibers can maintain the lumen of tubular bodies. The numerals 21-25 denote fibers loaded with therapeutic agents." To the extent the allegations in paragraph 38 attempt to characterize the '296 patent, Boston Scientific denies that characterization. Boston Scientific denies the remaining allegations in paragraph 38.

39. Boston Scientific admits that a portion of the '296 patent states "In yet another fabrication embodiment, a pre-existing fiber is loaded through a spinneret and through the coagulation bath. The liquid polymer emulsion is added in a 'T' or 'Y' junction and coats the fiber before entering a coagulation bath. Thus concentric coatings are applied to the fiber, with each coating having the ability to contain a different therapeutic agent(s) as shown in FIG. 4. The coating polymer may be the same or different from the core polymer. There may be molecules attached to the core fiber to increase the adhesion of the coating polymer." To the extent the allegations in paragraph 39 attempt to characterize the '296 patent, Boston Scientific denies that characterization. Boston Scientific denies the remaining allegations in paragraph 39.

40. Boston Scientific admits that a portion of the '296 patent states "In certain embodiments, the spinneret may have a non-circular shape, thereby forming fibers with any desired cross-sectional shape. This is true of the core fiber as well as the coating polymers." To the extent the allegations in paragraph 40 attempt to characterize the '296 patent, Boston Scientific denies that characterization. Boston Scientific denies the remaining allegations in paragraph 40.

41. Boston Scientific admits that a portion of the '296 patent states "Preferably, the diameter of the fibers will be from about 60 microns to about 80 microns." To the extent the allegations in paragraph 41 attempt to characterize the '296 patent, Boston Scientific denies that characterization. Boston Scientific denies the remaining allegations in paragraph 41.

42. Boston Scientific admits that a portion of the '296 patent states "For fibers that contain one or more therapeutic agents, the agent or agents may include a growth factor, an immunodulator [sic], a compound that promotes angiogenesis, a compound that inhibits angiogenesis, an anti-inflammatory compound, an antibiotic, a cytokine, an anti-coagulation agent, a procoagulation agent, a chemotactic agent, an agents that promotes apoptosis, an agent that inhibits apoptosis, a mitogenic agent, a radioactive agent, a contrast agent for imaging studies, a viral vector, a polynucleotide, therapeutic genes, DNA, RNA, a polypeptide, a glycosaminoglycan, a carbohydrate, a glycoprotein." To the extent the allegations in paragraph 42 attempt to characterize the '296 patent, Boston Scientific denies that characterization. Boston Scientific denies the remaining allegations in paragraph 42.

43. Boston Scientific admits that a portion of the '296 patent states "The term therapeutic agent in this invention also includes radioactive materials used to help destroy harmful tissues such as tumors in the local area, or to inhibit growth of healthy tissues, such as in current stent applications; or markers to be used in imaging studies." To the extent the allegations in paragraph 43 attempt to characterize the '296 patent, Boston Scientific denies that characterization. Boston Scientific denies the remaining allegations in paragraph 43.

44. Boston Scientific admits that a portion of the '296 patent states "In another embodiment, fibers can be loaded with a drug of interest and used in stents or other medical devices where mechanical strength is required. The stents can be woven in such a manner as to have loaded

fibers intermingled with unloaded fibers if needed for mechanical properties." To the extent the allegations in paragraph 44 attempt to characterize the '296 patent, Boston Scientific denies that characterization. Boston Scientific denies the remaining allegations in paragraph 44.

45. Boston Scientific admits that a portion of the '296 patent states "Fibers can also be used in conjunction with commercially available stents to deliver drugs at the placement site. In this case, the fibers would not provide any mechanical support, but would only serve as a drug delivery reservoir." To the extent the allegations in paragraph 45 attempt to characterize the '296 patent, Boston Scientific denies that characterization. Boston Scientific denies the remaining allegations in paragraph 45.

F. BSX'S INTERACTIONS WITH TISSUEGEN

46. Boston Scientific denies the allegations in paragraph 46.

47. Boston Scientific admits that, on January 11, 2007, the prosecuting attorney for U.S. Patent Application No. 11/395964 to Strickler and Tenney (the "Strickler Application") submitted an Information Disclosure Statement to the examiner of the Strickler Application that listed, among other documents, "6,596,296 B1" to "Nelson et al.," "2004/0028655 A1" to "Nelson et al.," and "2005/0106211 A1" to "Nelson et al." Boston Scientific admits that the Strickler Application is titled "Medical devices containing multi-component fibers." To the extent the allegations in paragraph 47 attempt to characterize the Strickler Application, Boston Scientific denies that characterization. Boston Scientific admits that a portion of the '296 patent states "fibers can be loaded with a drug of interest and used in stents or other medical devices where mechanical strength is required" and "Fibers can also be used in conjunction with commercially available stents to deliver drugs at the placement site. In this case, the fibers would not provide any mechanical support, but would only serve as a drug delivery reservoir." To the extent the

allegations in paragraph 47 attempt to characterize the '296 patent, Boston Scientific denies that characterization. Boston Scientific denies the remaining allegations in paragraph 47.

48. Boston Scientific admits that, in the 2006 to 2007 timeframe, Mr. Bluni held the titles of Vice President and Cardiovascular Chief Patent Counsel at Boston Scientific. Boston Scientific admits that, in March 2006, Mr. Bluni held the title of Assistant Secretary at Boston Scientific Scimed, Inc. Boston Scientific admits that Mr. Bluni signed a Power of Attorney dated March 7, 2006, which was transmitted with the Strickler Application on March 31, 2006. Boston Scientific denies the remaining allegations in paragraph 48.

49. Boston Scientific admits that, during the 2007 to 2010 timeframe and further, Boston Scientific Limited ("BSL") was a subsidiary of Boston Scientific. Boston Scientific denies the remaining allegations in paragraph 49.

50. Boston Scientific admits that an International search report (the "Search Report") that was submitted during the prosecution of the Strickler Application states, on its face, that its "Date of Mailing" was January 20, 2009, the "International application No." was PCT/US2007/007778, and that the "Applicant" was Boston Scientific Limited. Boston Scientific admits that the Search Report identifies "US 6 596 296 B1 (NELSON KEVIN D [US] ET AL)." Boston Scientific admits that the Search Report identifies "page 3 line 26 – page 4, line 21" and "examples 6-9" of "WO 2004/098503 A (UNIV TEXAS [US]; NELSON KEVIN D [US]; CROW BRENT B [US])." Boston Scientific admits that a portion of International Patent Publication No. WO/2004/098503 states "fibers can be loaded with a drug of interest and used in stents or other medical devices where mechanical strength is required" and "Fibers can also be used in conjunction with commercially available stents to deliver drugs at the placement site. In this case, the fibers would not provide any mechanical support, but would only serve as a drug delivery

reservoir." To the extent the allegations in paragraph 52 attempt to characterize International Publication No. WO 2004/098503, Boston Scientific denies that characterization. Boston Scientific denies the remaining allegations in paragraph 50.

51. Boston Scientific denies the allegations in paragraph 51.

52. Boston Scientific denies the allegations in paragraph 52.

53. Boston Scientific admits that, on or about October 16, 2008, Mary Beth Moynihan and Kevin Ballinger met with numerous people at the 2008 Transcatheter Cardiovascular Therapeutics ("TCT") Symposium, including Dr. Nelson. Boston Scientific admits that, in or about 2008, Ms. Moynihan held the title of Vice President, New Business Development in Interventional Cardiology. Boston Scientific admits that, in or about 2008, Mr. Ballinger held the title of Vice President of R&D and Program Management for Peripheral Interventions. Boston Scientific admits that, in the 2008 to 2009 timeframe, Ms. Moynihan and Mr. Ballinger had a work email address that included the domain "bsci.com." Boston Scientific denies the remaining allegations in paragraph 53.

54. Boston Scientific admits that Ms. Moynihan and Mr. Ballinger met with Dr. Nelson, at Dr. Nelson's request, to allow Dr. Nelson to introduce TissueGen and TissueGen's request for investment. Boston Scientific is without knowledge or information sufficient to form a belief regarding the remaining allegations in paragraph 54, and therefore denies them.

55. Boston Scientific admits that, on November 12, 2008, Ms. Moynihan emailed Dr. Nelson from her work email address. Boston Scientific admits that a portion of the November 12, 2008 email states "It was nice to meet you at TCT and receive an overview of your technology and plans. As we mentioned at the end of the meeting, Kevin and I wanted to take some time to consider your technology and request. As we mentioned during the meeting, BSC has decided not

to make passive equity investments in early stage technologies. While we think that your technology and ideas are interesting, Tissue Gen is not currently at a stage in which it makes sense for BSC to invest." To the extent the allegations in paragraph 55 attempt to characterize the November 12, 2008 email, Boston Scientific denies that characterization. Boston Scientific denies the remaining allegations in paragraph 55.

56. Boston Scientific admits that, on April 17, 2009, Ms. Moynihan received, through her work email address, an email from Dr. Nelson. Boston Scientific admits that a portion of the April 17, 2009 email states "more information." To the extent the allegations in paragraph 56 attempt to characterize the April 17, 2009 email, Boston Scientific denies that characterization. Boston Scientific denies the remaining allegations in paragraph 56.

57. Boston Scientific admits that, on April 23, 2009, Ms. Moynihan emailed Dr. Nelson. Boston Scientific admits that a portion of the April 23, 2009 email states "additional information." To the extent the allegations in paragraph 57 attempt to characterize the April 23, 2009 email, Boston Scientific denies that characterization. Boston Scientific admits that, on April 24, 2009, Dr. Nelson emailed Ms. Moynihan a presentation that related to technology for peripheral stents wherein the entire stent was biodegradable. Boston Scientific denies the remaining allegations in paragraph 57.

58. Boston Scientific denies the allegations in paragraph 58.

59. Boston Scientific denies the allegations in paragraph 59.

60. Boston Scientific denies the allegations in paragraph 60.

61. Boston Scientific admits that certain current and former employees of Boston Scientific are aware of Boston Scientific's non-infringement positions relating to the '296 patent. Boston Scientific denies the remaining allegations in paragraph 61.

62. Boston Scientific admits that, during the April 30, 2010 to October 2, 2015 timeframe, Ms. Moynihan held the positions of Vice President, Corporate Strategy and Research and Senior Vice President, Enterprise Strategy and Marketing. Boston Scientific admits that, during the April 30, 2010 to October 2, 2015 timeframe, Mr. Ballinger held the positions of EVP and Global President, Interventional Cardiology. Boston Scientific denies the remaining allegations in paragraph 62.

G. THE SYNERGY BP STENTS

63. Boston Scientific admits that, in January 2015, Boston Scientific submitted to the FDA premarket approval (PMA) No. P150003 seeking approval of the Synergy everolimus-eluting platinum chromium coronary stent. Boston Scientific admits that PMA No. P150003 was amended on January 20, March 10, March 26, April 15, June 17, July 7, and July 22, 2015. Boston Scientific admits that, on October 2, 2015, the FDA issued an Approval Order for PMA No. P150003. Boston Scientific denies the remaining allegations in paragraph 63.

64. Boston Scientific admits that Boston Scientific built SYNERGY Stents in the United States before October 2, 2015 for use in studies. Boston Scientific admits that paragraph 64 purports to recite portions of a paper titled "The SYNERGY Biodegradable Polymer Everolimus Eluting Coronary Stent: Porcine Vascular Compatibility and Polymer Safety Study" (the "Study"). Boston Scientific admits that a portion of the Study states "SYNERGY is a novel platinum chromium alloy stent that delivers abluminal everolimus from an ultrathin poly-lactide-co-glycide (PLGA) biodegradable polymer" and "Three SYNERGY stents were used: nominal SYNERGY manufactured in either Maple Grove, MN or Galway, Ireland or the SYNERGY FHU stent." To the extent the allegations in paragraph 64 attempt to characterize the Study, Boston Scientific denies that characterization. Boston Scientific denies the remaining allegations in paragraph 64.

65. Boston Scientific admits that paragraph 65 appears to be reciting portions of Boston Scientific's website available at the URL: https://www.bostonscientific.com/en-US/products/stents--coronary/bioabsorbable-polymer-stent.html. Boston Scientific admits that a portion of the website states "The SYNERGY BP Stent was the first FDA-approved drug-eluting stent with abluminal bioabsorbable polymer coating available in the U.S. It was designed to address the challenges associated with permanent polymer stents such as inflammation, neoatherosclerosis and late stent thrombosis." To the extent the allegations in paragraph 65 attempt to characterize the website, Boston Scientific denies that characterization. Boston Scientific denies the remaining allegations in paragraph 65.

66. Boston Scientific admits that paragraph 66 appears to be reciting portions of the SSED for the PMA No. P150003/S058. Boston Scientific admits that a portion of the SSED states "The SYNERGY and XYNERGY XD stents are comprised of a Platinum Chromium Alloy (PtCr). Similar to other metallic stents manufactured by Boston Scientific, the stent component is laser cut into a specific geometric pattern which consists of serpentine rings connected by links that are highly polished to a uniform rounded surface." To the extent the allegations in paragraph 66 attempt to characterize the SSED, Boston Scientific denies that characterization. Boston Scientific denies the remaining allegations in paragraph 66.

67. Boston Scientific admits that paragraph 67 appears to be reciting portions of the SSED for the PMA No. P150003/S058. BSC admits that a portion of the SSED states "Three (3) separate stent models were designed in specific size ranges. A stent model is defined as a variation of a specific geometry pattern designed for various vessel diameters. The three models are defined below: ● Small Vessel (SV): 2.25 mm, 2.50 mm, and 2.75 mm ● Workhorse (WH): 3.00 mm and 3.50 mm ● Large Vessel (LV): 4.00 mm, 4.50 and 5.00mm." To the extent the allegations in

paragraph 67 attempt to characterize the SSED, Boston Scientific denies that characterization. Boston Scientific denies the remaining allegations in paragraph 67.

68. Boston Scientific admits that Boston Scientific has described the struts of the SYNERGY Stents as "ultra-thin." Boston Scientific denies the remaining allegations in paragraph 68.

69. Boston Scientific admits that the strut thickness for the Small Vessel model of the SYNERGY Stents is 74 µm (0.0029 inches).

70. Boston Scientific admits that the strut thickness for the Workhorse model of the SYNERGY Stent is 79 µm (0.0031 inches).

71. Boston Scientific admits that the strut thickness of the Large Vessel model of the SYNERGY Stents is 81 µm (0.0032 inches).

72. Boston Scientific admits that paragraph 72 appears to be reciting portions of the SSED for the PMA No. P150003/S058. Boston Scientific admits that a portion of the SSED states "SYNERGY and SYNERGY XD are abluminally coated with a bioabsorbable coating. The coating consists of bioabsorbable PLGA polymer and everolimus. The PLGA polymer provides controlled and sustained release of available everolimus through the intended time frame, during which the polymer is reabsorbed into the body." To the extent the allegations in paragraph 72 attempt to characterize the SSED, Boston Scientific denies that characterization. Boston Scientific denies the remaining allegations in paragraph 72.

73. Boston Scientific admits that paragraph 73 appears to be reciting portions of Boston Scientific's website available at the URL: https://www.bostonscientific.com/en-US/products/stents--coronary/bioabsorbable-polymer-stent.html. Boston Scientific admits that a portion of the website states "The SYNERGY BP Stent provides synchronous drug elution and

polymer absorption; the polymer is absorbed shortly after the drug elution is complete at 3-months, providing rapid healing and freedom from long-term polymer exposure." To the extent the allegations in paragraph 73 attempt to characterize the website, Boston Scientific denies that characterization. Boston Scientific denies the remaining allegations in paragraph 73.

74. Boston Scientific admits that paragraph 74 appears to be reciting portions of Section 3.0 of Boston Scientific's PMA Application. Boston Scientific admits that a portion of Section 3.0 of Boston Scientific's PMA Application states "On a cellular level, everolimus inhibits, in a reversible manner, growth factor-stimulated cell proliferation. On a molecular level, everolimus forms a complex with the cytoplasmic protein FKBP-12. In the presence of everolimus, the growth factor-stimulated phosphorylation of p70 S6 kinase and 4E-BP1 is inhibited. The latter proteins are key proteins involved in the initiation of protein synthesis. Since phosphorylation of both p70 S6 kinase and 4E-BP1 is under the control of FRAP (FKBP-12-rapamycin associated protein, also called mTOR, mammalian target of rapamycin) this finding suggests that, the everolimus-FKBP-12 complex binds to and thus interferes with the function of FRAP. FRAP is a key regulatory protein which governs cell metabolism, growth and proliferation. Disabling FRAP function explains the cell cycle arrest at the late G1 stage caused by everolimus." To the extent the allegations in paragraph 74 attempt to characterize the PMA Application, Boston Scientific denies that characterization. Boston Scientific denies the remaining allegations in paragraph 74.

H. BSX'S POST-SUIT ACTIONS

75. The allegations in paragraph 75 are legal conclusions to which no answer is required. To the extent that an answer is required, Boston Scientific admits that 35 U.S.C. § 315 bars Boston Scientific from filing a petition for *inter partes* review of the '296 patent. Boston Scientific denies the remaining allegations in paragraph 75.

76. Boston Scientific admits that, on May 11, 2020, Boston Scientific filed an answer (D.I. 40) to Plaintiffs' Original Complaint that included a "First Separate Defense" of "Invalidity." Boston Scientific admits that Boston Scientific's answer (D.I. 40) to Plaintiffs' Original Complaint did not include a counterclaim for invalidity of the '296 patent or a counterclaim for noninfringement of the '296 patent, but Boston Scientific denied all allegations of infringement. Boston Scientific denies the remaining allegations in paragraph 76.

77. Boston Scientific admits that Boston Scientific has continued to import and sell SYNERGY Stents since November 2017 because they do not infringe any valid claim of the '296 patent. Boston Scientific denies the remaining allegations in paragraph 77.

COUNT I: DIRECT INFRINGEMENT

78. Boston Scientific incorporates by reference its responses to each and every allegation of the prior paragraphs as if fully set forth herein.

79. Boston Scientific denies the allegations in paragraph 79.

80. Boston Scientific denies the allegations in paragraph 80.

81. Boston Scientific denies the allegations in paragraph 81.

82. Boston Scientific denies the allegations in paragraph 82.

83. Boston Scientific denies the allegations in paragraph 83.

84. Boston Scientific denies the allegations in paragraph 84.

85. Boston Scientific denies the allegations in paragraph 85.

86. Boston Scientific denies the allegations in paragraph 86.

COUNT II: INDIRECT INFRINGEMENT

87. Boston Scientific incorporates by reference its responses to each and every allegation of the prior paragraphs as if fully set forth herein.

88. Boston Scientific denies the allegations in paragraph 88.

89. Boston Scientific denies the allegations in paragraph 89.

90. Boston Scientific denies the allegations in paragraph 90.

91. Boston Scientific denies the allegations in paragraph 91.

COUNT III: ENHANCED DAMAGES

92. Boston Scientific denies the allegations in paragraph 92.

93. Boston Scientific denies the allegations in paragraph 93.

94. Boston Scientific denies the allegations in paragraph 94.

RESPONSE TO PRAYER FOR RELIEF

The Prayer for Relief by the Plaintiffs states no allegations that require an answer from Boston Scientific. To the extent that an answer is required, Boston Scientific denies that the Plaintiffs are entitled to any such relief and denies all allegations of the Prayer for Relief.

SEPARATE DEFENSES

By asserting a defense herein, Boston Scientific does not assume a burden of proof or persuasion not otherwise required by applicable law. Boston Scientific sets forth the following separate defenses:

FIRST SEPARATE DEFENSE

(NON-INFRINGEMENT)

1. Boston Scientific does not infringe, and has never infringed, any valid claim of U.S. Patent No. 6,596,296 (the "'296 patent").

SECOND SEPARATE DEFENSE

(INVALIDITY)

2. The claims of the '296 patent are invalid for failure to satisfy the requirements of the United States patent laws embodied in 35 U.S.C. § 100, et seq., including 35 U.S.C. §§ 102

and 103. The claims are also invalid under 35 U.S.C. § 112 for lack of written description and indefiniteness.

THIRD SEPARATE DEFENSE

(LACHES)

3. Plaintiffs are barred from relief under the doctrine of laches.

FOURTH SEPARATE DEFENSE

(WAIVER)

4. Plaintiffs are barred from relief under the doctrine of waiver.

FIFTH SEPARATE DEFENSE

(LIMITATION ON DAMAGES)

5. Plaintiffs' claims are barred in whole or in part for failure to comply with the requirements of 35 U.S.C. § 287.

SIXTH SEPARATE DEFENSE

(LACK OF STANDING)

6. The Board of Regents for the University of Texas System lacks standing to bring claims for infringement of the '296 patent against Boston Scientific.

SEVENTH SEPARATE DEFENSE

(FAILURE TO STATE CLAIM)

7. Plaintiffs have failed to state a claim upon which relief may be granted.

RESERVATION OF DEFENSES

8. Boston Scientific reserves all affirmative defenses under Fed. R. Civ. P. 8(c), the patent laws of the United States, and any other defenses at law or in equity, that may now or in the future be available based on discovery or any other factual investigation concerning this case.

DEMAND FOR JURY TRIAL

Pursuant to Fed. R. Civ. P. 38(b), Boston Scientific demands a trial by jury for all issues so triable.

PRAYER FOR RELIEF

Boston Scientific respectfully requests:

A. That the Court dismiss with prejudice the First Amended Complaint and enter judgment that the Plaintiffs take nothing by this action;

B. That the Court enter judgment that Boston Scientific does not infringe, and has never infringed, any valid claim of the ’296 patent;

C. That the Court enter judgment that the asserted claims of the ’296 patent are invalid;

D. That the Court determine that this case is exceptional and award Boston Scientific its costs, attorneys’ fees, and litigation expenses incurred in this action pursuant to 35 U.S.C. § 285, including interest;

E. That the Court award Boston Scientific its costs, attorneys’ fees, and litigation expenses incurred in this action under any applicable basis;

F. That the Court award Boston Scientific any other relief that the Court deems just and proper.

Dated August 30, 2022

Respectfully submitted,

FARNAN LLP

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